EXHIBIT A

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 53
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY20C0100	3. EFFECTIVE DATE 09 Aug 2020	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011534693	

5. ISSUED BY	CODE W911QY	6. ADMINISTERED BY (If other than Item 5)	CODE S2206A
W6QK ACC-APG NATICK CONTRACT NG DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code)	8. DELIVERY [ ] FOB ORIGIN [X] OTHER (See below)
MODERNATX, INC [redacted] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578	9 DISCOUNT FOR PROMPT PAYMENT
	10 SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: — ITEM Section G
CODE 6RP85 — FACILITY CODE	

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE HQ0337
See Schedule		DEFENSE F NANCE AND ACCOUNT NG SERVICE DFAS - COLUMBUS CENTER (HQ0337) NORTH ENTITLEMENT OPERATIONS P.O. BOX 182317 COLUMBUS OH 43218-2266	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [X] 10 U.S.C. 2304(c)(2) [ ] 41 U.S.C. 253(c)( )	14. ACCOUNTING AND APPROPRIATION DATA See Schedule

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				
			15G. TOTAL AMOUNT OF CONTRACT		$1,525,000,000.00

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(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
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X	C	DESCRIPTION/ SPECS./ WORK STATEMENT	19 - 27	X	J	LIST OF ATTACHMENTS	52 - 53
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17 [ ] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18 [ ] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number W911QY20R0043 including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
	[redacted] / BRANCH CHIEF TEL: EMAIL: [redacted]

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B.	20C. DATE SIGNED
BY [redacted] (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	11-Aug-2020

Section A - Solicitation/Contract Form

A.1 The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for up to 500 million SARS-CoV-2 mRNA-1273 Vaccine doses (100 µg) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All doses of mRNA-1273 Vaccine referenced herein are 100 µg doses. All doses will be delivered in a multi- dose vial with a volume sufficient for 10 doses per vial.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001					$0.00

SARS-CoV-2 mRNA-1273 Vaccine
FFP
The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.
PROJECT: Operation Warp Speed

NET AMT $0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AA		15,000,000	Each	$12.25	$183,750,000.00

15M Doses
FFP
FOB: Origin (Shipping Point)
PURCHASE REQUEST NUMBER: 0011534693
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT $183,750,000.00

ACRN AA $183,750,000.00
CIN: GFEBS001153469300001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AB		22,000,000	Each	$12.25	$269,500,000.00

22M Doses
FFP

FOB: Origin (Shipping Point)
PURCHASE REQUEST NUMBER: 0011534693
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT $269,500,000.00

ACRN AB $269,500,000.00
CIN: GFEBS001153469300002

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AC		30,000,000	Each	$12.25	$367,500,000.00

30M Doses
FFP
FOB: Destination
PURCHASE REQUEST NUMBER: 0011534693
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT $367,500,000.00

ACRN AA $367,500,000.00
CIN: GFEBS001153469300003

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AD		33,000,000	Each	$12.25	$404,250,000.00

33M Doses
FFP
FOB: Destination
PURCHASE REQUEST NUMBER: 0011534693
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT $404,250,000.00

ACRN AA $404,250,000.00
CIN: GFEBS001153469300004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		1	Job		$0.00 TBN

Vendor Managed Inventory
FFP
a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F.
b. (b) (4) [redacted]
FOB: Destination
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT $0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003					$0.00

EUA or BLA Incentive
FFP
This is an incentive CLIN and will be earned only if an Emergency Use Authorization (EUA) or Biologics License Application (BLA) is obtained no later than 31 January 2021.
PROJECT: Operation Warp Speed

NET AMT $0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AA		15,000,000	Each	$3.00	$45,000,000.00

EUA or BLA Incentive
FFP
If earned, this incentive shall be paid at final acceptance of subCLIN 0001AA.
FOB: Destination
PSC CD: 6505

NET AMT $45,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AB		22,000,000	Each	$3.00	$66,000,000.00

EUA or BLA Incentive
FFP
If earned, this incentive shall be paid at final acceptance of subCLIN 0001AB.
FOB: Destination
PSC CD: 6505

NET AMT $66,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AC		30,000,000	Each	$3.00	$90,000,000.00

EUA or BLA Incentive
FFP
If earned, this incentive shall be paid at final acceptance of subCLIN 0001AC.
FOB: Destination
PSC CD: 6505

NET AMT $90,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AD		33,000,000	Each	$3.00	$99,000,000.00

EUA or BLA Incentive
FFP
If earned, this incentive shall be paid at final acceptance of subCLIN 0001AD.
FOB: Destination
PSC CD: 6505

NET AMT $99,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		1	Job		NSP

Technical Data
FFP
The contractor shall deliver technical Data IAW Contract Data Requirements List (CDRL) IAW deliveries in Section C.4 and Section J, Exhibit A.
FOB: Destination
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001					$0.00
OPTION	SARS-CoV-2 mRNA-1273 Vaccine				

FFP
The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.
PROJECT: Operation Warp Speed

NET AMT $0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001AA		33,200,000	Each	$16.50	$547,800,000.00
OPTION	33.2M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001AB		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001AC		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002		1	Job		$0.00 TBN
OPTION	Vendor Managed Inventory FFP a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. b. (b) (4) FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001					$0.00
OPTION	SARS-CoV-2 mRNA-1273 Vaccine FFP The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed				
				NET AMT	$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001AA		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) (b) (4) b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001AB		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) [redacted] b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001AC		33,200,000	Each	$16.50	$547,800,000.00
OPTION	33.2M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) [redacted]. b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002		1	Job		$0.00 TBN
OPTION	Vendor Managed Inventory FFP a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. b. (b) (4) [redacted] FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				

NET AMT $0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001					$0.00
OPTION	SARS-CoV-2 mRNA-1273 Vaccine FFP The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed				

NET AMT $0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AA		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AB		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AC		33,200,000	Each	$16.50	$547,800,000.00
OPTION	33.2M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002		1	Job		$0.00 TBN
OPTION	Vendor Managed Inventory FFP The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. (b) (4) FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001					$0.00
OPTION	SARS-CoV-2 mRNA-1273 Vaccine FFP The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed				
				NET AMT	$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AA		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AB		33,400,000	Each	$16.50	$551,100,000.00
OPTION	33.4M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AC		33,200,000	Each	$16.50	$547,800,000.00
OPTION	33.2M Doses FFP a. If executed, the option shall be awarded upon EUA or no later than (b) (4) . b. The government shall provide (b) (4) notification to exercise the option. FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002		1	Job		$0.00 TBN
OPTION	Vendor Managed Inventory FFP The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. b. (b) (4) FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				

NET AMT $0.00

Section C - Descriptions and Specifications

STATEMENT OF WORK
LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE

C.1 **SCOPE**. The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 Background. In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 Objective: The objective of this effort is to obtain the following:

a. Base Period: Large scale manufacturing of 100 million vaccine doses
b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.2 **APPLICABLE DOCUMENTS**.

C.2.1 Federal Documents:

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General. (https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS**. Independently, and not as an agent of the USG, in accordance with the Proposal submitted by ModernaTX, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)"), dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services,

qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 **Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 22013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within [redacted] of a scheduled FDA audit or within [redacted] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [redacted] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall

provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [redacted] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 **CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 22013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [redacted] of a scheduled FDA audit or within [redacted] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [redacted] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [redacted] of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but

not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 **CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [redacted] of a scheduled FDA audit or within [redacted] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [redacted] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [redacted] of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 **CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 22013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [redacted] of a scheduled FDA audit or within [redacted] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [redacted] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [redacted] of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 **CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 22013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [redacted] of a scheduled FDA audit or within [redacted] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [redacted] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [redacted] of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 **CLIN 0002: Data Deliverables**. The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, Bulk mRNA, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior

management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance.

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 Manufacturing Development Plan. The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

C.5 **Administration**.

C.5.1 Post Award Teleconference. The contractor shall host a Post Award Teleconference within 7 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 Post Award Kickoff Meeting. The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 Bi-Weekly Teleconference. The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 Daily "Check-In". The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 **Security**.

C.6.1 Access and General Protection/Security Policy and Procedures. The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 Security Program and Plan. The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and, submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.

C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

C.7 **CLIN 0002 Vendor Managed Inventory (VMI)**. The Contractor shall provide the capability to store the vaccine for up to 52 weeks, up to 100M doses of mRNA-1273 vaccine, in accordance with product labeling. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations . (b) (4) . The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within (b) (4) of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. . BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within (b) (4) of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations (b) (4) in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. (b) (4)

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 (b) (4) Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. (b) (4) Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

Section D - Packaging and Marking

D.1 Vaccine markings and labeling will be in accordance with FDA and will be finalized through a contract modification.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	N/A	N/A	N/A	N/A
0001AA	Origin	Government	Origin	Government
0001AB	Origin	Government	Origin	Government
0001AC	Destination	Government	Destination	Government
0001AD	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	N/A	N/A	N/A	N/A
0003AA	Destination	Government	Destination	Government
0003AB	Destination	Government	Destination	Government
0003AC	Destination	Government	Destination	Government
0003AD	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
1001	N/A	N/A	N/A	N/A
1001AA	Destination	Government	Destination	Government
1001AB	Destination	Government	Destination	Government
1001AC	Destination	Government	Destination	Government
1002	Destination	Government	Destination	Government
2001	N/A	N/A	N/A	N/A
2001AA	Destination	Government	Destination	Government
2001AB	Destination	Government	Destination	Government
2001AC	Destination	Government	Destination	Government
2002	Destination	Government	Destination	Government
3001	N/A	N/A	N/A	N/A
3001AA	Destination	Government	Destination	Government
3001AB	Destination	Government	Destination	Government
3001AC	Destination	Government	Destination	Government
3002	Destination	Government	Destination	Government
4001	N/A	N/A	N/A	N/A
4001AA	Destination	Government	Destination	Government
4001AB	Destination	Government	Destination	Government
4001AC	Destination	Government	Destination	Government
4002	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-16	Responsibility For Supplies	APR 1984

E1. Inspection:

Initial quality inspection of Filled Drug Product (FDP) shall occur when the Contractor performs release testing to confirm that products complies with Contractor's release specifications and criteria. Contractor will submit in WAWF to the Contracting Officer or the duly authorized representative of the Government with a Certificate of Analysis for quality inspection of all deliverables. Initial Inspection under this contract will be performed at the Contractor's facility, or the subcontractor facility, by the BARDA Contracting Officer Technical Representative (COTR).

Final inspection of product shall occur when the Government inspects each shipment of product delivered to it hereunder for visible damage and quantity within (b) (4) of such delivery. In the event Contractor supplies any product to the Government and it is established that such Product was damaged or does not include the required quantities at the time of delivery, the Government shall promptly notify Contractor in writing within [redacted]. Final inspection shall be conducted at the CDC location identified as destination.

In the event the USG requires storage of the FDP to a Vendor Managed Inventory (VMI) location, final quantity inspection shall be conducted by submission into WAWF of shipping or other documentation confirming quantity to VMI location. Final physical inspection of the FDP shall be conducted upon receipt of product to USG location.

Inspection of all reports and Contract Data Requirement List (CDRL) under this contract will be performed at Destination by duly authorized representative of the Government.

E.2 Acceptance

a. Acceptance at origin shall occur at (b) (4) [redacted]. Acceptance at destination shall occur (b) (4) [redacted] Regardless of where acceptance occurs, the contractor is responsible for final delivery of Filled Drug Product (FDP) to a government designated CDC location.

b. Acceptance under this agreement will be performed by Army Contracting Command Aberdeen Proving Ground (ACC-APG) Natick Contracting Division (NCD) Contracting Officer.

c. Acceptance of services under VMI SubCLINs (List CLINS) shall occur upon satisfactory physical and quantity inspection of FDP upon delivery at USG designated CDC location.

d. The parties acknowledge that acceptance may depend on the compliance with the Contractor's product specifications. The KO and COR may prior to acceptance consult with FDA under its authority under Public Law 115-92 to determine whether the material to be delivered meets the Contractor's product specifications. To this end, Contractor agrees to provide a letter to FDA authorizing the Government to engage in dialog with FDA about the ultimate compliance of this product with the Contractor's product specifications prior to acceptance. BARDA/COR will accept product according to the approved Product Acceptance Procedure.

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)			N/A	N/A
			N/A FOB: Origin (Shipping Point)	
			N/A FOB: Origin (Shipping Point)	
			N/A FOB: Destination	
			N/A FOB: Destination	
			N/A FOB: Destination	
			N/A	N/A
			N/A FOB: Destination	
			N/A FOB: Destination	
			N/A FOB: Destination	
			N/A FOB: Destination	
			(b) (4) (b) (6) (b) (4) [redacted] [redacted] [redacted] DC 20024 202-260-6798 FOB: Destination	(b) (4)
			N/A	N/A
			N/A FOB: Destination	

(b) (4)	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A	N/A
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A	N/A
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A	N/A
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	
	N/A FOB: Destination	

CLAUSES INCORPORATED BY REFERENCE

52.211-17	Delivery of Excess Quantities	SEP 1989
52.242-15	Stop-Work Order	AUG 1989
52.247-34	F.O.B. Destination	NOV 1991

F.1 The contractor shall ship mRNA-1273 vaccines to designated locations in up to (b) (4) in the United States. The contractor shall be responsible for secure shipment of all vaccine product whether acceptance is conducted at origin or destination.

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 021202020212040000066464325 5 S.0074658.5.6 6100.9000021001
COST CODE: A5XAH
AMOUNT: $955,500,000.00

AB: 021202020212040000066464325 5 S.0074658.5.6.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: $269,500,000.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001AA	GFEBS001153469300001	$183,750,000.00
	0001AC	GFEBS001153469300003	$367,500,000.00
	0001AD	GFEBS001153469300004	$404,250,000.00
AB	0001AB	GFEBS001153469300002	$269,500,000.00

CLAUSES INCORPORATED BY REFERENCE

252.204-7006	Billing Instructions	OCT 2005
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and

(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

COMBO

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

Invoice and receiving report document type

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

N/A

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC**	S2206A

Inspect By DoDAAC	S2206A / BARDA
Acceptor	W911QY
Ship To	TDB

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(b) (6) / DCMA Boston-AFAW, Administrative Contracting Officer / (b) (6)

(2) Contact the WAWF helpdesk at (b) (6), if assistance is needed.

(End of clause)

FOR REFERANCE:

DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_htm/current/PGI204_71.htm#payment_instructions

G.1 GOVERNMENT CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

Procuring Contracting Officer:
(b) (6)
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

Contract Specialist:

(b) (6)
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)
ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.4 PLACES OF PERFORMANCE

ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

G.6 PERFORMANCE BASED PAYMENT

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0008, Performance-based Payment Milestone Table. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

CLIN	PERIOD	AMOUNT
0001AA	BASE	$ 90,210,000
0001AA	BASE	$ 132,308,000
0001AA	BASE	$ 180,420,000
0001AA	BASE	$ 198,462,000
TOTAL		$ 601,400,000
(b) (4)		

(b) (4)	[redacted]	[redacted]
[redacted]		[redacted]

Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0009, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0009.

Section H - Special Contract Requirements

H.1 Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Name	Title
(b) (6)	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

H.2 Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

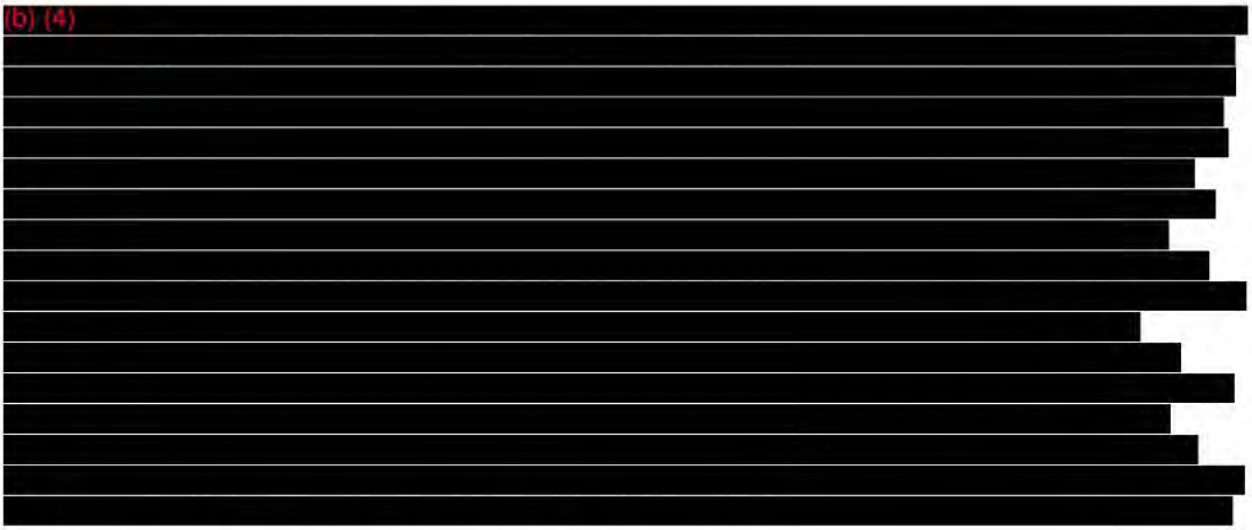
ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.



H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

(b) (4) [redacted]

(b) (4) [redacted]

[redacted]

H.10 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government (b) (4) [redacted], of:

i. any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

ii. any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

iii. any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

(b) (4) [redacted]

(b) (4) [redacted]

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. (b) (4) [redacted].

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

H.14 Novation

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUN 2020
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions On Subcontractor Sales To The Government	JUN 2020
52.203-7	Anti-Kickback Procedures	JUN 2020
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	JUN 2020
52.203-13	Contractor Code of Business Ethics and Conduct	JUN 2020
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	JUN 2020
52.204-1	Approval of Contract	DEC 1989
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUN 2020
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-18	Commercial and Government Entity Code Maintenance	JUL 2016
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities.	JUL 2018
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2019
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	JUN 2020
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	NOV 2015
52.210-1	Market Research	JUN 2020
52.215-2	Audit and Records--Negotiation	JUN 2020
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data--Modifications	JUN 2020
52.215-13	Subcontractor Certified Cost or Pricing Data--Modifications	JUN 2020
52.215-14	Integrity of Unit Prices	JUN 2020
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -- Modifications	JUN 2020
52.217-4	Evaluation Of Options Exercised At The Time Of Contract Award	JUN 1988
52.217-7	Option For Increased Quantity-Separately Priced Line Item	MAR 1989
52.217-8	Option To Extend Services	NOV 1999
52.219-8	Utilization of Small Business Concerns	OCT 2018

52.219-28	Post-Award Small Business Program Rerepresentation	MAY 2020
52.222-1	Notice To The Government Of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-19	Child Labor -- Cooperation with Authorities and Remedies	JAN 2020
52.222-21	Prohibition Of Segregated Facilities	APR 2015
52.222-26	Equal Opportunity	SEP 2016
52.222-35	Equal Opportunity for Veterans	JUN 2020
52.222-36	Equal Opportunity for Workers with Disabilities	JUN 2020
52.222-37	Employment Reports on Veterans	JUN 2020
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	JAN 2019
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	JUN 2020
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	JUN 2020
52.227-1 Alt I	Authorization And Consent (JUN 2020) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	JUN 2020
52.227-11	Patent Rights--Ownership By The Contractor	MAY 2014
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	MAY 2014
52.232-23	Assignment Of Claims	MAY 2014
52.232-25	Prompt Payment	JAN 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-13	Bankruptcy	JUL 1995
52.243-1	Changes--Fixed Price	AUG 1987
52.243-7	Notification Of Changes	JAN 2017
52.244-5	Competition In Subcontracting	DEC 1996
52.245-9	Use And Charges	APR 2012
52.249-2	Termination For Convenience Of The Government (Fixed-Price)	APR 2012
52.249-8	Default (Fixed-Price Supply & Service)	APR 1984
52.249-14	Excusable Delays	APR 1984
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.211-7003	Item Unique Identification and Valuation	MAR 2016
252.222-7006	Restrictions on the Use of Mandatory Arbitration Agreements	DEC 2010
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2014
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	FEB 2014
252.227-7016	Rights in Bid or Proposal Information	JAN 2011

252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	JAN 2011
252.227-7019	Validation of Asserted Restrictions--Computer Software	SEP 2016
252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	JUN 1995
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 2016
252.232-7007	Limitation Of Government's Obligation	APR 2014
252.244-7000	Subcontracts for Commercial Items	JUN 2013

CLAUSES INCORPORATED BY FULL TEXT

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 5 days for; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days for Options 1 and 2, 60 days for Option 3 and 4 before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 20 months.

(End of clause)

52.232-32 PERFORMANCE-BASED PAYMENTS (APR 2012)

(a) Amount of payments and limitations on payments. Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.

(b) Contractor request for performance-based payment. The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (l) and (m) of this clause.

(c) Approval and payment of requests.

(1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.

(2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the 30th day after receipt of the request for performance-based payment by the designated payment office. However, the designated payment office is not required to provide

payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquiries into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.

(3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.

(d) Liquidation of performance-based payments.

(1) Performance-based finance amounts paid prior to payment for delivery of an item shall be liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.

(2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.

(e) Reduction or suspension of performance-based payments. The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (h) and (i) of this clause).

(2) Performance of this contract is endangered by the Contractor's --

(i) Failure to make progress; or

(ii) Unsatisfactory financial condition.

(3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.

(f) Title.

(1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract

(2) "Property," as used in this clause, includes all of the following described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices:

(i) Parts, materials, inventories, and work in process;

(ii) Special tooling and special test equipment to which the Government is to acquire title;

(iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment and other similar manufacturing aids, title to which would not be obtained as special tooling under subparagraph (f)(2)(ii) of this clause; and

(iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.

(3) Although title to property is in the Government under this clause, other applicable clauses of this contract (e.g., the termination or clauses) shall determine the handling and disposition of the property.

(4) The Contractor may sell any scrap resulting from production under this contract, without requesting the Contracting Officer's approval, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.

(5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor shall obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based payments, title shall vest in the Contractor for all property (or the proceeds thereof) not --

(i) Delivered to, and accepted by, the Government under this contract; or

(ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.

(7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.

(g) Risk of loss. Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. If any property is lost (see 45.101), the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(h) Records and controls. The Contractor shall maintain records and controls adequate for administration of this clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.

(i) Reports and Government access. The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor's performance of this contract for administration of this clause.

(j) Special terms regarding default. If this contract is terminated under the Default clause,

(1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and

(2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which

the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.

(k) Reservation of rights.

(1) No payment or vesting of title under this clause shall --

(i) Excuse the Contractor from performance of obligations under this contract; or

(ii) Constitute a waiver of any of the rights or remedies of the parties under the contract.

(2) The Government's rights and remedies under this clause --

(i) Shall not be exclusive, but rather shall be in addition to any other rights and remedies provided by law or this contract; and

(ii) Shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.

(l) Content of Contractor's request for performance-based payment. The Contractor's request for performance-based payment shall contain the following:

(1) The name and address of the Contractor;

(2) The date of the request for performance-based payment;

(3) The contract number and/or other identifier of the contract or order under which the request is made;

(4) Such information and documentation as is required by the contract's description of the basis for payment; and

(5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.

(m) Content of Contractor's certification. As required in paragraph (l)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that --

(1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer;

(2) (Except as reported in writing on _____), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;

(3) There are no encumbrances (except as reported in writing on _____) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;

(4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated _____; and

(5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and

the amount of all payments under the contract will not exceed any limitation in the contract.

(End of Clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

https://www.acquisition.gov/content/regulations

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

Document Type	Description	Page #	Date
Exhibit A	CDRLs	14	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	2	23 July 2020
Attachment 0002	Security Plan	6	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	1	7 August 2020
Attachment 0005	(b) (4)	1	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	2	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	1	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	15	7 August 2020

Exhibit A
Contract Data Requirements List (CDRL)

Data Item #	Title of Data Item	Subtitle	Date
A001	Quality Audit Finding and Response Record (QAFRR)	BARDA Audit Findings Report	18-Jul-20
A002	Quality Audit Finding and Response Record (QAFRR)	FDA Audit Findings Report	18-Jul-20
A003	Contractor Furnished Material (CFM) Report	Monthly Inventory Report	18-Jul-20
A004	Quality Program Plan	Quality Program Plan	18-Jul-20
A005	Task Directive Documentation	Shipping Documentation - Finished Drag Products (FDP)	18-Jul-20
A006	Task Directive Documentation	Expiring Item Report	18-Jul-20
A007	Contractor's Personnel Roster	Key Personnel Listing	18-Jul-20
A008	Status Report	Monthly Technical Progress Report	18-Jul-20
A009	Contract Summary Report	Final Technical Report	18-Jul-20
A010	Supply Chain Risk Management Plan	Supply Chain Resiliency Plan (SCRP)	18-Jul-20
A011	Contractor's Risk Management Plan	Risk Management Plan (RMP)	18-Jul-20
A012	Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration	Vendor Managed Inventory Plan/SOP	18 Jul 20
A013	Internal Contractor Technical Data	Manufacturing Reports and Dose Tracking Projections/Actuals	18-Jul-20
A014	Certificate of Compliance (Analysis)	Product Acceptance Report	18-Jul-20
A015	N/A	-	-
A016	Accident Incident Report	Incident Report	18-Jul-20
A017	Internal Contractor Technical Data Report	FDA Correspondence	18-Jul-20
A018	Acquisition Support Documentation	Press Releases	18-Jul-20
A019	Contractor's Standard Operating Procedures	Security Plan	18-Jul-20
A020	Conference Agenda	Conference Agenda	18-Jul-20

A021	Report, Record of Meeting/Minutes	Meeting Minutes	18-Jul-20
A022	Presentation Material	Presentation Material	18-Jul-20
A023	N/A	-	-
A024	Operations Security (OPSEC) Plan	Operational Security (OPSEC) SOP/Plan	18 Jul 20
A025	Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration (FDA)	Manufacturing Development Plan	18 Jul 20

EXHIBIT B

No. 2020-2329

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MODERNA TX, INC., fka Moderna Therapeutics, Inc.,

Appellant,

v.

ARBUTUS BIOPHARMA CORPORATION,

Appellee.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in No. IPR2019-00554.

NON-CONFIDENTIAL DECLARATION OF SHAUN RYAN IN SUPPORT OF APPELLANT MODERNA TX, INC.'S STANDING TO APPEAL

I, Shaun Ryan, hereby declare as follows:

1. I am Senior Vice President and Deputy General Counsel for Appellant ModernaTX, Inc. ("Moderna"). I submit this Declaration in support of Moderna's standing in this appeal. I have personal knowledge of the facts set forth in this Declaration and, if called as a witness, could and would testify competently to such facts under oath.

2. Since its founding in 2010, Moderna has worked to build a leading mRNA technology platform to develop and test candidates for mRNA-based vaccines and therapies spanning several therapeutic areas. Moderna created this platform to improve the pharmaceutical properties of its mRNA medicines. The platform consists of three core areas: mRNA technologies, delivery technologies, and manufacturing processes.

3. Moderna most recently harnessed its own proprietary mRNA technology, delivery technologies, and manufacturing processes to develop its COVID-19 vaccine, mRNA-1273. Moderna was able to leverage its experience in vaccines to move rapidly to design and manufacture material for the mRNA Phase 1 clinical trial. Shortly after the SARS-CoV-2 genetic sequence was determined in January 2020 by the Chinese government, Moderna developed mRNA-1273, a lipid-nanoparticle (LNP)–encapsulated mRNA vaccine expressing the prefusion-stabilized spike glycoprotein. mRNA-1273 uses an mRNA payload delivered by a

lipid carrier particle, [redacted]

[redacted] Proprietary formulation information [redacted]

[redacted]. A timeline of Moderna's efforts in developing mRNA-1273 is presented at https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19. Ex. 1.

4. As of September 23, 2020, Moderna had made concrete plans for the release of mRNA-1273. Just days after the Chinese authorities released the genetic sequence of the novel coronavirus, Moderna finalized the sequence for mRNA-1273. On March 16, 2020, Moderna and its government partners began a Phase 1 study for mRNA-1273 using the payload and lipid carrier particle ultimately approved. It began Phase 2 enrollment in May 2020 and Phase 3 enrollment in July 2020.

5. Preliminary Phase 1 results showing safety and efficacy were published in July 2020. On August 11, 2020, Moderna entered into a Supply Agreement with the Army Contracting Command of the U.S. Department of Defense for the manufacture and delivery of an initial 100 million doses of mRNA-1273 for $1.225 billion, plus additional incentive payments. Moderna began manufacturing the vaccine for commercial sale in June 2020.

6. By September 2020, Moderna had spent hundreds of millions of dollars developing the vaccine. Thus, as of September 23, 2020, there was a strong likelihood that Moderna would sell mRNA-1273 commercially.

7. On December 18, 2020, Moderna received emergency use authorization in the United States for mRNA-1273 and began shipping the vaccine to the U.S. government immediately. In January 2021, Moderna received additional emergency use authorizations for mRNA-1273 for Canada, Israel, the European Union, and the United Kingdom.

8. Moderna's first commercial shipments of mRNA-1273 manufactured in the United States went to the U.S. government—in keeping with Moderna's commitment to assisting the national response to the pandemic—and are subject to 28 U.S.C. § 1498. Moderna is also currently supplying foreign governments with mRNA-1273 manufactured abroad. [redacted]

[redacted]

[redacted]

[redacted]

Moderna's plans for future commercial activity

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] **Moderna's plans for future commercial activity** [redacted]

[redacted]

9. In view of Arbutus's statements and actions, which I describe below, there is a substantial risk that Arbutus may bring an infringement action relating to Moderna's COVID-19 vaccine, mRNA-1273. Although Moderna has communicated to Arbutus that its COVID-19 vaccine rests on its own innovations and does not practice the '069 patent, there is nonetheless a substantial risk of litigation concerning Moderna's vaccine given Arbutus's aggressive stance regarding its patent portfolio, regardless of the merits of its claims.

10. Arbutus has long proclaimed that its patent estate covers virtually all lipid nanoparticle ("LNP") delivery systems. For example, their former CEO, Mark Murray, has stated:

- "In our view what they are reporting as theirs appears to be dominated by our intellectual property." Ex. 2 (*Forbes,* May 2017).
- "There is an umbrella of intellectual property here that we think dominates the field…. Even if there was a particular lipid that was unique we still don't think these things escape the broad umbrella." Ex. 2 (*Forbes,* May 2017).
- "We invented, developed and dominate the field of LNP." Ex. 2 (*Forbes,* May 2017).
- "From our perspective anything we've seen in the scientific or patent literature clearly falls under the scope of our intellectual property …

> Nothing they've done is free of our IP." Ex. 3 (*Financial Times*, September 2017).

Moderna has tracked these statements and Arbutus's position regarding the expansive scope of its IP rights.

11. As of September 23, 2020, Arbutus's statements and actions showed that Moderna's activities regarding mRNA-1273 created a significant risk that Arbutus would sue for infringement of the '069 patent. Arbutus and its affiliate, Genevant Sciences, have consistently taken the position with Moderna that it requires a license to its patents, including the '069 patent. Arbutus has not granted Moderna a covenant not to sue on the '069 patent. Thus, while Moderna strongly disagrees that any infringement assertion has merit, given Arbutus's longstanding aggressive stance, there was a substantial risk as of September 23, 2020, and there continues to be a substantial risk, that Arbutus will bring an infringement action concerning mRNA-1273.

12. The uncertainty created by Arbutus's aggressive stance regarding the scope of its patents is causing harm to Moderna's valuation in the eyes of investors. Although Moderna has repeatedly communicated to its investors and the public that it does not believe that mRNA-1273 practices Arbutus's patents, Ex. 4 (https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-patent-trial-and-appeal-board-ptab-ruling), [redacted] Confidential communication [redacted]. When the PTAB's final written decision

was issued, Moderna's stock price fell 10% in one day—equivalent to over $1 billion in market capitalization at the time—even though there was no actual infringement action against Moderna, Ex. 5 (https://www.fool.com/investing/2020/07/24/tiny-arbutus-biopharma-wins-patent-litigation-figh.aspx).

13. A finding that the '069 patent's claims were invalid would eliminate the risk that Moderna could be sued for infringement for making, using, and selling its mRNA-1273 COVID-19 vaccine under that patent.

14. Further, Moderna is a current licensee to U.S. Patent No. 8,058,069 ("'069 patent") under four product sublicenses (which do not include COVID-19 vaccines). As part of a November 12, 2012 agreement, Protiva Biotherapeutics, Inc. ("Protiva"), then a wholly owned subsidiary of Arbutus, licensed the '069 patent to Acuitas Biotherapeutics ("Acuitas"). Ex. 6 at 8, 10, Sch. D Protiva Patents at 13 (Protiva/Acuitas 2012 License); Ex. 7 (Arbutus press release). Acuitas redacted the attached copy of the agreement to remove financial terms.

[redacted]

[redacted]

[redacted] License agreement terms [redacted]

[redacted]

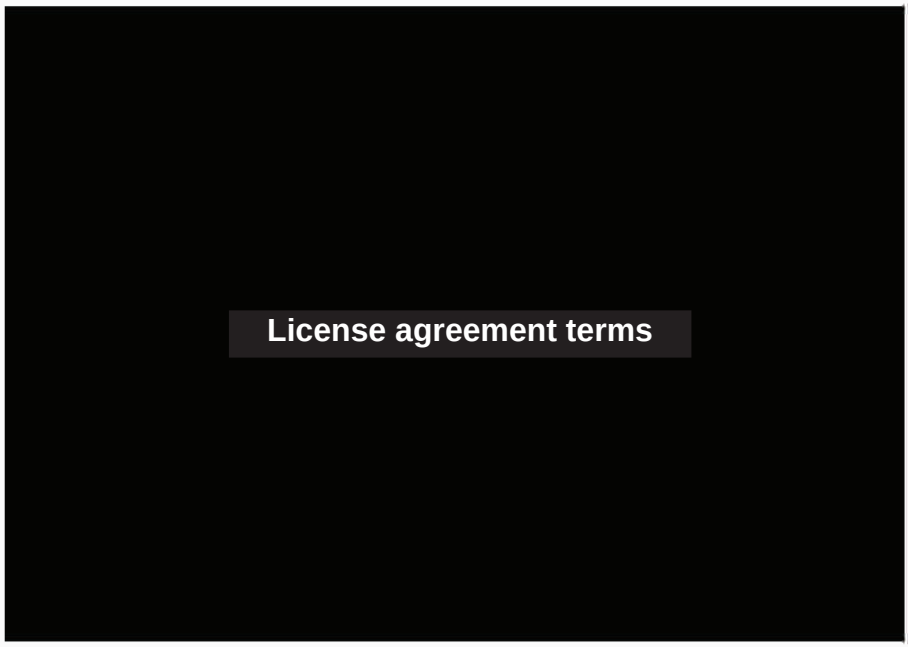
[redacted]

[redacted] License agreement terms [redacted] Protiva merged into Arbutus in January 2018.

15. Acuitas sublicensed the Protiva/Arbutus pre-April 15, 2010 LNP technology, including the '069 patent, to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, Respiratory Syncytial Virus ("RSV"), and Zika virus. Exs. 8-11 (Acuitas 2015-2016 sub-licenses to Moderna).

[redacted] License agreement terms [redacted]

16. Moderna has milestone obligations pursuant to the Acuitas sublicenses to the '069 patent for certain clinical activities. For example, Section 5.2 of each sublicense sets out the milestone payment obligations for Licensed Products:



License agreement terms

17. Moderna has made Phase 1 milestone payments of Number under all four sublicense agreements for Phase 1 projects with LNP ranges that overlap with the ranges claimed in certain patents in the licensed portfolio, including the '069 patent. Those projects generated Phase 1 safety and tolerability data in early candidates that would support additional dose escalation or clinical advancements. Although these projects have not so far been pursued to further phases, they have not been abandoned either and still remain as options Moderna may pursue depending on a variety of factors, including cost and freedom to operate. Additionally, Moderna's plans for research and development . Because the carrier particle in these early candidates practices,

among other licensed technology, the '069 patent, if and when Phase II clinical trials are initiated [redacted: Moderna's plans for research and development], a [redacted: Number] milestone payment will come due for each target.

18. The royalty and milestone obligations owed to Acuitas for the use of the '069 patent, among others, increase the financial burdens on the RSV, Chikungunya, Zika, and Influenza A programs and impact Moderna's ability to attract partners for those viral targets. If the '069 patent is found to be invalid, Moderna's financial obligations to Acuitas for practicing the '069 patent would extinguish.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed at Cambridge, Massachusetts, this 22nd day of February, 2020.

By: 
Shaun Ryan